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Date: 11/21/02 By: JM Hewner

In re Application of: Charles David Claude	Examiner: R. DeWitty
Serial No.: 09/822,952	Art Unit: 1616
Filed: March 30, 2001	
Title: CONTROLLED MORPHOLOGIES IN POLYMER DRUG FOR RELEASE OF DRUGS FROM POLYMER FILMS	

Commissioner for Patents
Washington, DC 20231

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RESPONSE TO OFFICE ACTION

Dear Examiner DeWitty:

This is a response to the final Office Action dated August 9, 2002, which has a shortened statutory period for response that ended on November 9, 2002. The accompanying petition requests a one-month extension of time, extending the period to respond to December 9, 2002.

REMARKS

Claims 1-13, 16, 17, and 44-47 are pending in this application. The numbered paragraphs below correspond to the Examiner's numbered paragraphs.

1. Claims 1-17 and 44-47 stand rejected under 35 U.S.C. § 112, first paragraph. Claims 14 and 15 were canceled in the previous response dated May 2, 2002. Support for the amended claims can be found in the specification at page 7, lines 3-12 and page 8,

lines 1-5. These passages are cited as exemplary of the claimed subject matter and are not intended to be a complete recitation of all instances of the claimed subject matter. Withdrawal of the rejection is respectfully requested.

2. Claims 1, 2, 4, 5, 10, 11 and 17 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Eury et al. (U.S. Patent No. 5,605,696). Eury et al. teach that “[a] selected therapeutic drug is preferably intimately mixed with the selected polymeric material so as to uniformly disperse the therapeutic drug in the polymeric material” (col. 3, lines 26-29). Eury et al. further disclose the addition of a prosigen into the drug loaded polymeric material (col. 4, lines 60-63 and col. 5, lines 1-9). The polymeric material is analogous to the bulk phase of the Applicant’s specification. Nowhere do Eury et al. disclose **“a drug incorporated into the drug-enriched phase, the drug having preferential solubility for the polymeric drug-enriched phase than the bulk polymer phase wherein the bulk polymeric phase is substantially or completely devoid of the drug,”** as recited by Claim 1. Accordingly, Claim 1 is patentably allowable over Eury et al. Claims 2, 4, 5, 10, 11 and 17 depend directly from Claim 1 and are therefore patentably allowable for at least the same reason. Withdrawal of the rejection and allowance of the claims is respectfully requested.

3. Claims 1-17 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Hossainy et al. (U.S. Patent No. 6,153,252). As correctly indicated by the Examiner, Hossainy et al. do disclose top coatings to delay the release of a therapeutic agent (col. 9, lines 5-9). However, Hossainy et al. fail to teach **“a bulk polymer phase; a polymeric drug-enriched phase within the bulk polymer phase, the polymeric drug-enriched phase being substantially or completely insoluble in the bulk polymer phase; and a drug incorporated into the drug-enriched phase, the drug having preferential solubility for the polymeric drug-enriched phase than the bulk polymer phase wherein the bulk polymeric phase is substantially or completely devoid of the drug,”** as recited by Claim 1. Accordingly, Claim 1 is patentably allowable over Hossainy et al. Claims 2-13, 16 and 17 depend directly and indirectly from Claim 1 and are allowable for at least the same reason. Claims 14 and 15 have been previously canceled. Withdrawal of the rejection and allowance of the claims is respectfully requested.

4. Claims 44-47 stand rejected under the same rejections as claims 1-17. As noted above, Eury and Hossainy do not teach each of the limitations of the new claims.

CONCLUSION

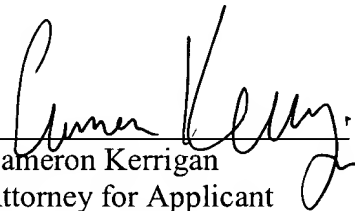
Claims 1-13, 16, 17 and 44-47 are pending in this application.

Examination and allowance of the claims are respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0323.

Dated: 11/24/02

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Respectfully submitted,


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